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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,241	10/23/2000	Nicole Barie	K 168	9230

7590

02/23/2004

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/694,241

Applicant(s)

BARIE ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 6-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/03 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3 and 6-15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for T-BSA and dextran, does not reasonably provide enablement for TRIMID-modified aminodextran. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant has not even mentioned TRIMID-modified aminodextran in the specification, such that there is a clear lack of direction or guidance is using it with the present invention, which would make the invention highly unpredictable with the use of that molecule. In addition, the lack of working examples with this molecule, combined with the above factors, would require undue experimentation of one of ordinary skill in the art to make and use the invention commensurate with the full scope of the claims.

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Chai-Gao et al. (US Pat. 5,858,802).

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Swan et al. teach a process for the preparation of crosslinked matrices containing covalently immobilized chemical species and unbound releasable chemical species. According to the reference, polymers may be covalent immobilized in an insoluble 3-D crosslinked matrix, which is preferably formed as a coating upon a surface. A desired chemical species and a polymeric coupling compound such as a photoderivatized polymer having multiple photoreactive groups are brought into proximity to each other. Upon activation, bonding occurs (abstract and cols. 2-3). Dextran may be the polymer from which the coupling compound is derived (col. 3, line 62). In addition, the photoreactive groups of the reference may be diazirines, such as 3-trifluoromethyl-3-phenyldiazirine (col. 5, line 55).

Hubbell et al. teach interfacial polymerization to form a membrane on the surface of a biological membrane. Tissue is directly coated with photoinitiator, which is immersed in macromer solution, and immediately irradiated. This results in a thin polymer coat (col. 9). Dextran may be the macromer of the reference (col. 11, lines 19-54). However, neither Swan et al. nor Hubbell et al. teach the use of TRIMID modification or T-BSA.

Chai-Gao et al. teach a method for making a device including a substrate and at least one biologically active substance bound to the surface of the substrate. The device is obtained by simultaneous or sequential reaction of the substrate and of the substance with a bifunctional coupling agent in which one of the functional groups may be photoactivated. The photoactivator is preferably a TRIMID-modified protein, such as T-BSA (cols. 3-5).

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator of Chai-Gao et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Chai-Gao et al. as the photoinitiator, with the only difference being

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that the diazirine in Chai-Gao et al. is substituted. Since the diazarines of Chai-Gao et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazarine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would have further been obvious to use aminodextran instead of dextran as the polymer because the two molecules differ only by 1 substitution, which is not viewed as detrimentally altering the binding capability of the dextran.

8. Claims 3 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Wessa et al. (WO 97/43631)

Swan et al. and Hubbell et al. teach coating processes, as previously discussed. However, the references do not teach TRIMID modification, the use of BSA or polyimide, or application to biological sensors.

Wessa et al. teach a process for producing a sensor for detecting proteins. The sensor consists of a sensor body, one surface of which is coated with a polymer layer with receptor molecules bonded to said polymer layer. The bond between the polymer and the receptor molecules is provided by a photoreactive molecule that is covalent to the lysine of a receptor molecule and inserted into the polyimide. The photoreactive molecule is preferably TRIMID. The modified protein, which may be T-BSA, is bound to the polymer layer by UV irradiation. The sensor of the reference may be used as a surface acoustic wave sensor, which is interpreted as an electromechanical sensor. In addition, wave sensors are also interpreted as mass sensitive, as a difference in mass on the sensor will affect the results in some manner.

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator and polyimide of Wessa et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al.

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states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazine to that of Wessa et al. as the photoinitiator, with the only difference being that the diazine in Chai-Gao et al. is substituted. Since the diazines of Wessa et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would have further been obvious to use aminodextran instead of dextran as the polymer because the two molecules differ only by 1 substitution, which is not viewed as detrimentally altering the binding capability of the dextran. In addition, it would have been obvious to apply the modified coating process of Wessa et al. and Swan et al. or Hubbell et al. to a biological sensor, as surface receptors are commonly used in sensing applications.

#### *Response to Arguments*

9. Applicant's arguments filed 12/15/03 have been fully considered but they are not persuasive.
10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).
11. Applicant's arguments fail to comply with 37 CFR 1.111(b) and (c) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. In

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addition, applicant's arguments do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

***Conclusion***

Claims 3 and 6-15 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

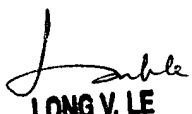
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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02/06/04